



LABORATORIO
DE MEDICAMENTOS
HERBOLARIOS

Barbadillo 416 Norte, Centro,
Guadalupe, N.L. 67100 México
Tels. (8) 367-3508 • 367-6976

INSIDE USA CALL
Ph. 888-293-4406
www.malabarusa.com

0266 '99 MAR 15 P2:00
March 1st, 1999

Rec'd
3/8/99

Victor Fratelli, Ph.D.

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW.,
Washington, DC 20204

Dear Dr. Fratelli,

Notice is hereby given pursuant to the requirements to Section 403(r) (6) (21 U.S.C. 343) (r) (6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and in the labeling in connection with the marketing of the Malabar Productos Naturales dietary supplements: Slimaid, Stressaid, Winterease, Pancreaid, Jointaid, Prostease, Menstrualaid, Kidnease, Gastritease, Liveraid, Sleepaid, Laxatease. These products were first marketed with these statements of nutritional support on February 19, 1999. Notification procedures and the statements of nutritional support as follows:

- **Name and Address of the manufacturer and packer:**
Malabar Productos Naturales S.A. de C.V.
Barbadillo #416 nte.
Guadalupe Centro
Guadalupe, N.L. 67100
México
- **Name and Address of the U.S. importer and distributor:**
Planet Earth Imports
715 "J" Street
Suite 307
San Diego, CA. 92101
U.S.A.

The statements of nutritional support are as follows:

1. Name (brand name) of dietary supplement: SLIMOID
 - Text of the statement: "A natural herbal dietary supplement traditionally designed to support a weight reduction program by regulating nervous eating, plus maintains water balance."
 - Name of the dietary ingredient that is subject to the statement:
 - i) White Zapote (*Casimiroa edulis*);
 - ii) Prickle-pear cactus (*Opuntia ficus indica*);
 - iii) Dandelion (*Taraxacum officinale*).
 - This product has the following NOTICE / WARNING:
"This product contains (Aloe Vera; Senna, *Cassia angustifolia*). Read and follow instructions carefully. Do not use if you have developed diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication or have a medical condition, consult your physician before using this product."
"Accompany this product with a program which includes diet modification and exercise."



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2. Name (brand name) of dietary supplement: STRESSAID
 - Text of the statement: "A natural supplement containing an ancient herb blend traditionally known for their calming properties, to help maintain normal blood pressure during stressful conditions."
 - Name of the dietary ingredient that is subject to the statement:
 - i) White Zapote (*Casimiroa edulis*);
 - ii) Tepozan (*Buddleja cordata*);
 - iii) *Salvadora* (*Solanum verbascifolium*)
 - iv) Mistletoe (*Viscum album*).
 - This product has the following NOTICE:
"Do not drive a motor vehicle or operate machinery after taking this product."
3. Name (brand name) of dietary supplement: WINTEREASE
 - Text of the statement: "A traditional blend of herbs formulated to support the regulation of changes in body temperature during weather variations."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Eucalypto (*Eucalytus globulus*)
 - ii) Mullein (*Gnaphallium berlandieri*)
 - iii) Wild marjoran (*Origanum vulgare*)
 - iv) Mint (*Mentha piperita*)
4. Name (brand name) of dietary supplement: PANCREAID
 - Text of the statement: "A herbal dietary supplement traditionally known to assist the pancreas function of maintaining normal blood sugar levels."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Prickle-pear cactus (*Opuntia ficus indica*)
 - ii) Fenugreek (*Trigonella foenum-graecum*)
 - iii) Tronadora (*Tecoma stans*)
5. Name (brand name) of dietary supplement: JOINTAID
 - Text of the statement: "Herbal formula traditionally used to support normal joint movement by maintaining natural properties. Assists in the removal of metabolic waste products from the body."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Wintergreen (*Gaultheria procumbens*)
 - ii) *Salvadora* (*Solanum verbascifolium*)
 - iii) Poke (*Phytolacca icosandra*)
 - iv) Tepozan (*Buddleja cordata*)
 - v) Horsetail (*Equisetum arvense*)



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6. Name (brand name) of dietary supplement: PROSTEASE
 - Text of the statement: "Herbal blend traditionally known to promote healthy circulation. Beneficial in promoting normal urination."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Nettle (*Urtica dioica*)
 - ii) Fennel (*Foeniculum vulgare*)
 - iii) Wintergreen (*Gaultheria procumbens*)
7. Name (brand name) of dietary supplement: MENSTRUALAID
 - Text of the statement: "A traditionally herbal dietary supplement with beneficial properties for regulating menstrual cycles and maintaining muscular tone."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Rue (*Ruta graveolens*)
 - ii) Parsley (*Petroselinum crispum*)
 - iii) Aloe (*Aloe vera*)
 - iv) Chamomile (*Matricaria chamomille*)
 - This product has the following NOTICE/WARNING: "This product contains (Aloe Vera). Read and follow instructions carefully. Do not use if you have developed diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication or have a medical condition, consult your physician before using this product."
8. Name (brand name) of dietary supplement: KIDNEASE
 - Text of the statement: "This traditionally herbal blend possesses natural properties that aid in the elimination of kidney waste."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Corn silk (*Zea mays*)
 - ii) Horsetail (*Equisetum arvense*)
 - iii) Parsley (*Petroselinum crispum*)
9. Name (brand name) of dietary supplement: GASTRITEASE
 - Text of the statement: "Unique blend of herbs traditionally used to help maintain proper acid levels in the stomach."
 - Name of the dietary ingredient that is subject to the statement:
 - i) Cuachalalate (*Amphipterygium adstringens*)
 - ii) Licorice (*Glycyrrhiza glabra*)
 - iii) Chamomile (*Matricaria chamomille*)
 - iv) Fennel (*Foeniculum vulgare*)
 - This product has the following NOTICE/WARNING: "This product contains (Cascara Sagrada, *Rhamnus Purshiana*). Read and follow instructions carefully. Do not use if you have developed diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication or have a medical condition, consult your physician before using this product."



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10. Name (brand name) of dietary supplement: LIVERAID

- Text of the statement: "Traditionally used to support healthy liver functions including maintenance of normal blood sugar level and break down of body wastes. Liveraid stimulates bile production to help remove waste products and digest fat."
- Name of the dietary ingredient that is subject to the statement:
 - i) Dandelion (*Taraxacum officinale*)
 - ii) Boldo (*Peumus boldus*)
 - iii) Tepozan (*Buddleja cordata*)

11. Name (brand name) of dietary supplement: SLEEPAID

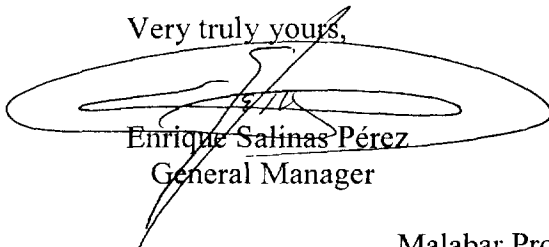
- Text of the statement: "A herbal dietary supplement to help keep you calm and restful. Sleepaid contains herbs which are known to be effective in promoting normal rest, even after stressful conditions. These herbs have a long history of use for their mild and effective properties."
- Name of the dietary ingredient that is subject to the statement:
 - i) White Zapote (*Casimiroa edulis*)
 - ii) Valerian (*Valeriana officinalis*)
 - iii) Linden flower (*Tilia occidentalis*)
- This product has the following NOTICE:
"Do not drive a motor vehicle or operate machinery after taking this product."

12. Name (brand name) of dietary supplement: LAXATEASE

- Text of the statement: "A herbal dietary supplement traditionally used to maintain regular digestion, to clean digestive tract and eliminate body wastes."
- Name of the dietary ingredient that is subject to the statement:
 - i) Aloe (*Aloe vera*)
 - ii) Prickle-pear cactus (*Opuntia ficus indica*)
 - iii) Dandelion (*Taraxacum officinale*)
- This product has the following NOTICE/WARNING: "This product contains (Aloe vera; Senna, *Cassia angustifolia*; Cascara, *Rhamnus purshiana*). Read and follow instructions carefully. Do not use if you have develop diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication or have a medical condition, consult your physician before using this product."

Thank you for your attention to this letter.

Very truly yours,



Enrique Salinas Pérez
General Manager

Malabar Productos Naturales S.A. de C.V.